

REMARKS

Applicants would like to thank Examiners Royds and Marschel for taking time to hold the above-recited telephone interview. In the Office Action mailed April 20, 2006, Claims 1-36 were pending for consideration. All of the claims were objected to and/or rejected on various statutory grounds, each of which is addressed in turn below. By the present amendment, Claims 1, 32, and 33 have been amended, claims 3-12, 25-28, and 34-36 have been canceled, and new claims 37-65 have been added. Support for the amendments of claims 1, 32, and 33 can be found in the original specification on page 13, line 28 to page 14, line 6. Support for the newly added claims 37-65 can be found throughout the original specification, and in particular in the following locations: original claims 1-31; page 11, line 13 to page 16, line 17; page 9, lines 13-15; page 22, line 28 to page 25, line 33. Applicants submit that no new matter has been added thereby.

It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the correctness of the Examiner's rejection. Accordingly, Claims 1, 13-24, 29-33 remain pending along with newly filed claims 37-65. Applicants respectfully submit that the present claims are allowable over the Patel '192 reference, and that the rejections in view thereof are now moot.

Provisional Statutory Double Patenting Rejection:

Claims 1-2 and 16-33 were provisionally rejected under 35 U.S.C. 101 as allegedly claiming the same invention as that of Claims 1-2 and 17-34 of copending U.S. Patent Application No. 11/122,788. Applicants assert that the currently amended claims are distinct from those of the '788 application and as such it is respectfully requested that this rejection be withdrawn. In the event that the Examiner chooses to maintain such rejection, the Applicants

request that it be held in abeyance until the claims of the present application have been finalized and allowed.

35 U.S.C. § 102 Rejections:

The Examiner has rejected Claims 1-16, 20-26, and 28-36 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,294,192 (hereinafter “Patel ‘192”), filed on February 26, 1999, in light of Stedman’s Medical Dictionary (1972, p.595 and 1400). The Applicants assert that the presently pending claims are distinct from and patentable over the cited reference.

The present invention claims a pharmaceutical composition including a therapeutically effective amount of a drug; and a solubilizer selected from the group consisting of selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, PEG-8 caprylic/capric glycerides, sorbitan monooleate, sorbitan monolaurate, PEG-20 sorbitan monopalmitate, PEG-20 sorbitan monostearate, PEG-20 sorbitan monooleate, glyceryl mono/dioleate, glyceryl caprylate/caprate, caprylic acid mono/diglycerides, and mono- and diacetylated monoglycerides, linoleoyl monoglycerides, lauroyl macrogol-32 glycerides, α -tocopherol, α -tocopherol acetate, α -tocopherol succinate, α -tocopherol polyethyleneglycol (200-8000 MW) succinate, α -tocopherol polyethylene glycol 400 succinate, d1- α -tocopherol polyethyleneglycol 1000 succinate, and d- α -tocopherol polyethyleneglycol 1000 succinate. The composition further includes a release modulator which synchronizes the release of the drug and the solubilizer.

The ‘192 Patent does not teach a composition with a release modulator or any other ingredient that is taught or suggested to have the ability to synchronize release of a drug and a solubilizer that are contained in the same dosage formulation. As such, the ‘192 patent does not teach each and every element of the present invention. Even assuming, *arguendo*, that the ‘192

Patent did coincidentally teach compositions having release rate modulators, the presently pending claims have been amended so as set forth specific solubilizers with which the release modulators can effectively perform such function. Teachings or suggestions of combinations that achieve such properties are clearly not found in the '192 patent.

As such, the Applicants submit that the asserted Patel '192 reference does not teach each and every element of the pending claims, and therefore it is respectfully requested that this rejection be withdrawn.

35 U.S.C. § 103 Rejections:

The Examiner has rejected Claims 1-36 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Patel '192 in light of Stedman's Medical Dictionary, and in view of U.S. Patent No. 6,458,373 (hereinafter "Lambert"), The Merck Index (Monograph 1882, 1989), U.S. Patent No. 6,309,663 (hereinafter "Patel '663"), U.S. Patent No. 6,623,755 (hereinafter "Chen"), and U.S. Patent No. 5,403,593 (hereinafter "Royce").

As discussed above, the '192 Patent does not teach each and every element of the pending claims. Additionally, as the '192 patent qualifies only as prior art under the provisions of 35 U.S.C. 102(e), and as the presently claimed invention was subject to an obligation of assignment, at the time of invention, and has in fact been assigned to the same entity as the '192 patent (i.e. commonly owned), Applicants respectfully submit that '192 patent is unavailable for assertion as a reference in an obviousness rejection of the present application under the provisions of 35 U.S.C. 103(c). Accordingly, Applicants respectfully submit that the present rejection based on the above-recited combination of references is improper and request that it be withdrawn.

CONCLUSION

In view of the foregoing, the Applicants believe that Claims 1, 13-24, 29-33 and 37-65 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 20th day of September, 2006.

Respectfully submitted,

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